

AMENDMENTS TO THE DRAWINGS

The attached replacement sheet of drawings includes Figures 7A and 7B, which replace sheet 12 containing Figures 7A and 7B.

Attachment: Replacement sheets

REMARKS

The present Office Action addresses claims 1-30, however claims 26-30 are withdrawn from consideration. Remaining claims 1-25 stand rejected.

Amendments to the Drawings

The Examiner objects to Figures 7A and 7B as being a dark color photograph. Applicants have amended these figures to bring them in compliance with 37 C.F.R. 1.121(d). No new matter has been added.

Amendments to the Claims

Applicants amend claim 1 to replace the language “opening in the distal end” with the language “substantially open distal end,” thereby providing proper antecedent basis for this limitation. This amendment does not alter the scope of claim 1, and no new matter is added.

Applicants also cancel withdrawn claims 26-30. Applicants reserve the right to pursue these claims in a divisional application.

Claim Objections

“Substantially”

The Examiner objects to claims 1 and 13 as being indefinite for using the term “substantially.” Specifically, the Examiner argues that the term “substantially” “is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.” Applicants respectfully disagree.

The Federal Circuit has long held that the use of the term “substantially” in claims is not indefinite, even where the term is not defined in the specification. In *Verve, LLC v. Crane Cams, Inc.* 311 F.3d 1116 (Fed. Cir. 2002), the Federal Circuit stated:

While reference to intrinsic evidence is primary in interpreting claims, the criterion is the meaning of words as they would be understood by

persons in the field of the invention. Patent documents are written for persons familiar with the relevant field; the patentee is not required to include in the specification information readily understood by practitioners, lest every patent be required to be written as a comprehensive tutorial and treatise for the generalist, instead of a concise statement for persons in the field. Thus resolution of any ambiguity arising from the claims and specification may be aided by extrinsic evidence of usage and meaning of a term in the context of the invention.

Id. at 1119-1120. The Court further explained that “[e]xpressions such as ‘substantially’ are used . . . in order to accommodate the minor variations that may be appropriate to secure the invention . . . and indeed may be necessary in order to provide the inventor with the benefit of his invention.” *Id.* at 1120. The Court thus held that the language “substantially constant wall thickness” was not indefinite.

Applicants also refer the Examiner to *Ecolab Inc. v. Envirochem, Inc.*, 264 F.3d 1358, 1367 (Fed. Cir. 2001), in which the Court likewise held that the term “substantially” is not indefinite. The Court stated that “like the term ‘about,’ the term ‘substantially’ is a descriptive term commonly used in patent claims to ‘avoid a strict numerical boundary to the specified parameter,’” quoting *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995). In *Liquid Dynamics Corp. v. Vaughn Co., Inc.*, 355 F.3d 1361 (Fed. Cir. 2004), the Court again held that the language a “substantial helical flow path” is not indefinite, and they construed the term in this case as a meaningful modifier implying “approximate” rather than “perfect.”

Accordingly, it is well established that the term “substantially” is not indefinite as used in claims, and therefore reconsideration and withdrawal of this objection is respectfully requested.

“About”

The Examiner also objects to claims 1, 6, 7, 13, 15, 16, 19-21, 23, and 24 as being indefinite for using the term “about.” Again, the Examiner argues that the term is not defined by the claim and the specification does not provide a standard for ascertaining the requisite degree. Applicants respectfully disagree.

As with the term “substantially,” the Federal Circuit has made it clear that the term “about” is

not indefinite and that a person having ordinary skill in the art will readily understand the meaning of this term. For example, in *Chemical Separation Technology Inc. v. United States*, 51 Fed. Cl. 771, 782-783 (Fed. Cir. 2002), the Federal Circuit held that the use of the language “a pH of about 5” “does not render the claim here indefinite, as illustrated by the fact that the Federal Circuit has, on several occasions, construed the scope of a range of “about” numbers in determining whether a patent was infringed.” The Court cited various cases that have held that claims employing the term “about” are definite. *See, e.g., Zoltek Corp.*, 48 Fed. Cl. at 300; *see also Eiselstein v. Frank*, 52 F.3d 1035, 1040 (Fed. Cir. 1995) (“the meaning of the word ‘about’ is dependent on the facts of a case, the nature of the invention, and the knowledge imparted by the totality of the earlier disclosure to those skilled in the art”); *Modine Mfg. Co. v. United States Int’l Trade Comm’n*, 75 F.3d 1545, 1554 (Fed. Cir. 1996) (“Although it is rarely feasible to attach a precise limit to ‘about’ the usage can usually be understood in light of the technology embodied in the invention.”), *cert. denied*, 518 U.S. 1005 (1996); *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1557 (Fed. Cir. 1983) (descriptive term “about,” when used to describe ranges in a patent, does not render a claim indefinite), *cert. denied*, 469 U.S. 851 (1984); *CPC International Inc. v. Archer Daniels Midland Co.*, 831 F. Supp. 1091, 1110 (D. Del. 1993) (“In the context of determining an appropriate tip speed for a particular vessel and agitator, a person skilled in the art would not find the term ‘about 600 cm/sec’ to be unclear.”), *aff’d*, 31 F.3d 1176 (Fed. Cir. 1994), *cert. denied*, 513 U.S. 1184, 130 L. Ed. 2d 1129, 115 S. Ct. 1176 (1995); *Zoltek Corp. v. United States*, 48 Fed. Cl. 290, 300 (Fed. Cl. 2000) (“The Court does not agree with Defendant’s contention that a precise limit must always be attached to the term ‘about.’”); *Syntex (U.S.A.), Inc. v. Paragon Optical Inc.*, 1987 U.S. Dist. LEXIS 14544, 7 U.S.P.Q.2D (BNA) 1001, 1038 (D. Ariz. 1987) (“‘About’ is not broad or arbitrary but rather is a flexible term with a meaning similar to ‘approximately.’”).

In all of the claims objected to in the present application, the term “about” precedes a numerical quantity and is included so as to avoid unnecessarily strict numerical boundaries. In all of these claims, a person of ordinary skill in the art would understand the proper limitations when examined in the context of this technology. Therefore, the term “about” is not indefinite and withdrawal of the objection is respectfully requested.

Rejections Pursuant to 35 U.S.C. §102

The Examiner rejects claims 1-3, 10-11, 21-22 and 25 pursuant to 35 U.S.C. §102(b) as being anticipated by WO 99/58066 of Altman et al. (“Altman”). Applicants respectfully disagree.

Independent claim 1 recites a tissue extraction and maceration device including an outer tube having an open distal end adapted to be placed on a tissue surface, and a shaft rotatably disposed within the outer tube. The shaft is movable between a first, proximal position in which the shaft is fully disposed within the outer tube, and a second, distal position in which a portion of a distal end of the shaft extends through the opening in the distal end of the outer tube. Claim 1 also recites a tissue harvesting tip formed on the distal end of the shaft and effective to excise a tissue sample, and a cutting member coupled to the shaft at a position proximal to the tissue harvesting tip and effective to macerate a tissue sample excised by the tissue harvesting tip.

The Examiner continues to assert that Altman discloses an outer tube (14) having an open distal end, a shaft (12) rotatably disposed within the outer tube (14) and movable between a first proximal position and second distal position exposing the distal end of the shaft from the outer tube (14), a tissue harvesting tip (50) disposed on the distal end of the shaft (12), and cutting members (13, 30, 35) coupled to the shaft proximal to the tissue harvesting tip. This is incorrect.

The Examiner’s rejection is flawed for several reasons. First, element 12 of Altman is a rotor, and element 14 is a sheath disposed around the rotor. While the Examiner is correct that the rotor (12) rotates within the sheath (14), the rotor (12) does not move between proximal and distal positions to expose a cutting blade formed on the distal end of the rotor (12). Rather, the rotor (12) is fixed longitudinally within the sheath (14) and it merely rotates to cut tissue suctioned into the sheath (14). Claim 1 specifically requires a shaft that is both rotatably disposed within an outer sheath *and* movable between proximal and distal positions. Since the rotor (12) does not move between proximal and distal positions within the sheath (14), the rotor cannot form the claimed shaft.

The only portion of the Altman device that moves between proximal and distal positions is the sheath (14), which is illustrated in FIG. 8A of Altman and reproduced herein. The sheath (14), however, cannot form both the claimed outer tube and a shaft rotatably disposed within the outer tube. The sheath (14) also cannot form the claimed shaft because it is not *both* rotatable and movable

proximally and distally, as required by claim 1. As shown FIG. 8A, the sheath (14) moves proximally and distally within an outer cylinder (63) to move opposed jaws (50) between the open and closed positions, as explained at page 11, lines 10-22 of Altman. The sheath cannot rotate within the outer cylindrical because “tabs 79 and 81 are anchored to sheath 14 at pivots 89 and 87, respectively.” (Altman, p. 11, lines 19-20.) This fixed attachment between the sheath (14) and the tabs (79, 81) clearly prevents the sheath from rotating. Altman therefore fails to disclose a shaft that is *both* rotatably disposed within an outer tube *and* that is movable between proximal and distal positions, as required by independent claim 1.

In sum, Altman discloses a rotor (12) that rotates and a sheath (14) that moves between proximal and distal positions. Claim 1, however, requires a shaft that is *both* rotatably disposed within an outer tube *and* that moves between proximal and distal positions. The rotor and the sheath of Altman are separate components that cannot be considered to form the claimed shaft. Neither of these components is *both* rotatable and movable between proximal and distal positions.

The Examiner is also incorrect in asserting that element 50 forms a tissue harvesting tip that is disposed on the distal end of the shaft, and that is exposed when the shaft is in a distal position. The opposed jaws (50) on the Altman device do not move with a shaft between proximal and distal positions. They are fixedly mated to the outer cylinder (63) by tabs (71, 73) attached at pivot points (75, 77). The tabs (71, 73) are pivotally mated to a second set of tabs (79, 81) which are attached to the sheath (14). As a result, when the sheath slides within the outer cylinder, the tabs move with the sheath to cause the jaws to pivot to open and close the jaws. The tabs do not pull the jaws in a proximal or distal direction. This is best illustrated in FIGS. 8B and 8C of Altman, which show the jaws in the open and closed positions, respectively. Neither jaws has moved proximally or distally relative to the outer cylinder (63).

Altman also fails to teach or even suggest an outer tube having a substantially open distal end that is adapted to be placed on a tissue surface. In the embodiment shown in FIG. 8A, the outer cylinder (63) is the only component that can form the outer tube. The sheath (14) cannot form the outer tube since it is disposed within the outer cylinder (63). The outer cylinder (63), however, cannot be placed on a tissue surface as it is positioned proximal of the jaws. That is, the jaws will prevent the distal end of the outer tube from being placed on a tissue surface.

Independent claim 1, as well as claims 2-3, 10-11, 21-22 and 25 which depend therefrom, therefore distinguish over Altman and represent allowable subject matter.

Rejections Pursuant to 35 U.S.C. §103


The Examiner rejects dependent claims 4-9, 12-20, and 23-24 pursuant to 35 U.S.C. §103(a) as being obvious over Altman in view of one of various references set forth in the Office Action. As explained above, Altman is deficient as a reference for several reasons, and thus claim 1 distinguishes over Altman. The remaining cited references fail to cure the deficiencies of Altman. Accordingly, claims 4-9, 12-20, and 23-24 are allowable at least because they depend from an allowable base claim.

Conclusion

In view of the remarks above, Applicants submit that all pending claims are now in condition for allowance, and allowance thereof is respectfully requested. Applicants encourage the Examiner to telephone the undersigned in the event that such communication might expedite prosecution of this matter.

Respectfully submitted,

Date: July 13, 2006



Lisa Adams, Reg. No. 44,238
Attorney for Applicant(s)

Nutter McClennen & Fish LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA 02210
Tel: (617)439-2550
Fax: (617)310-9550